

CLAIMS

1. Polymorphic Form C of base ondansetron,
5 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 14.97 and 20.86° 2 θ and
presents no peaks beneath 6.5° 2 θ .

2. Polymorphic Form D of base ondansetron,
10 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 11.29°; 14.58°; 17.16°;
18.89°; 20.28°; 21.22°; 25.06° and 27.49° 2 θ .

3. Polymorphic Form E of base ondansetron,
15 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 6.29°; 11.09°; 11.88°;
12.69°; 14.97° and a doublet at (24.96°; 25.17°) 2 θ .

4. Polymorphic form according to Claim 1,
20 characterised in that its powder X-ray diffraction pattern
also presents a peak at 25.50° 2 θ .

5. Polymorphic form according to Claim 4,
characterised in that its powder X-ray diffraction pattern
25 presents the following peaks:

2 θ (°)
7.18
10.96
13.13
14.97
16.08
16.42
19.73
20.86

20

21.82
24.08
24.70
25.50
26.73
27.59
28.97

6. Polymorphic form according to Claim 5, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 1.

5

7. Polymorphic form according to Claim 2, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2 θ (°)
5.58
7.10
7.26
10.77
10.92
11.29
13.23
13.65
14.58
14.74
15.23
15.38
15.92
16.22
16.48
17.16
17.86
18.89
20.28
20.71
21.22
21.98
22.84

21

23.53
24.12
24.75
25.06
26.03
26.17
26.56
26.79
27.49
27.91
28.75
29.41

8. Polymorphic form according to Claim 7, characterised in that presents a powder X-ray diffraction pattern in accordance with Figure 2.

5

9. Polymorphic form according to Claim 3, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2 θ (°)
6.29
7.06
10.50
11.09
11.88
12.69
13.10
13.57
14.97
16.33
16.93
17.40
18.58
19.28
20.71
21.08
21.28
22.10
24.12
24.71

22

24.96
25.17
25.73
26.65
26.93
28.18
28.53
29.34
29.76

10. Polymorphic form according to Claim 9, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 3.

5

11. Process for preparing the polymorphic form according to Claim 1, characterised in that it comprises:

- a) preparation of a saturated solution of base ondansetron at room temperature in dichloromethane;
- 10 b) precipitation of the crystalline form by addition of a C₅-C₇ alkane; and
- c) recovery of the crystalline form.

12. Process according to Claim 11, characterised
15 in that said C₅-C₇ alkane is n-hexane or n-pentane.

13. Process for preparing the polymorphic form according to Claim 2, characterised in that comprises:

- 20 a) dissolution of base ondansetron in a C₁-C₄ alcohol at reflux;
- b) addition of *t*-butyl-methyl-ether followed by cooling; and
- c) recovery of the crystalline form.

25 14. Process for preparing the polymorphic form according to Claim 3, characterised in that it comprises:

- a) dissolution of the ondansetron hydrochloride in a mixture of a C₁-C₃ alcohol and water;

- b) precipitation of the base ondansetron by basification of the solution;
- c) filtering the solid and washing with water;
- d) suspension of the water-moistened solid obtained in
- 5 stage c) with methanol at reflux with stirring; and
- e) recovery of the crystalline form.

15 15. Process according to any of claims 13 or 14, characterised in that said alcohol is methanol.

10

16. Process according to Claim 14, characterised in that the basification of stage b) is carried out by addition of an aqueous ammonia solution.

15 17. Pharmaceutical composition that includes a polymorphic form according to any of claims 1 to 10, in a therapeutically active amount and with a suitable amount of at least one excipient.

20 18. Polymorphic form according to any of claims 1 to 10 for use for manufacturing a drug for the treatment and prophylaxis of post-operative nausea and vomiting and for the control of nausea and vomiting induced by radiotherapy and cytotoxic chemotherapy.

25